container from which they are removed for use, the information required by paragraphs (e)(1) through (e)(6) of this section may appear in the outer container labeling only.

(f) The labeling for over-the-counter (OTC) test sample collection systems for drugs of abuse testing shall bear the following information in language appropriate for the intended users:

(1) Adequate instructions for specimen collection and handling, and for preparation and mailing of the specimen to the laboratory for testing.

(2) An identification system to ensure that specimens are not mixed up or otherwise misidentified at the laboratory, and that user anonymity is maintained.

(3) The intended use or uses of the product, including what drugs are to be identified in the specimen, a quantitative description of the performance characteristics for those drugs (e.g., sensitivity and specificity) in terms understandable to lay users, and the detection period.

(4) A statement that confirmatory testing will be conducted on all samples that initially test positive.

(5) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR part 1500 and any other warnings appropriate to the hazard presented by the product.

(6) Adequate instructions on how to obtain test results from a person who can explain their meaning, including the probability of false positive and false negative results, as well as how to contact a trained health professional if additional information on interpretation of test results from the laboratory or followup counseling is desired.

(7) Name and place of business of the manufacturer, packer, or distributor.

[41 FR 6903, Feb. 13, 1976, as amended at 45 FR 3750, Jan. 18, 1980; 45 FR 7484, Feb. 1, 1980; 47 FR 41107, Sept. 17, 1982; 47 FR 51109, Nov. 12, 1982; 48 FR 34470, July 29, 1983; 62 FR 62259, Nov. 21, 1997; 65 FR 18234, Apr. 7, 2000]

Subpart C—Requirements for Manufacturers and Producers

§ 809.20 General requirements for manufacturers and producers of in vitro diagnostic products.

(a) [Reserved]

(b) *Compliance with good manufacturing practices.* In vitro diagnostic products shall be manufactured in accordance with the good manufacturing practices requirements found in part 820 of this chapter and, if applicable, with § 610.44 of this chapter.

[41 FR 6903, Feb. 13, 1976, as amended at 42 FR 42530, Aug. 23, 1977; 43 FR 31527, July 21, 1978; 66 FR 31165, June 11, 2001]

§ 809.30 Restrictions on the sale, distribution and use of analyte specific reagents.

(a) Analyte specific reagents (ASR's) (§ 864.4020 of this chapter) are restricted devices under section 520(e) of the Federal Food, Drugs, and Cosmetic Act (the act) subject to the restrictions set forth in this section.

(b) ASR's may only be sold to:

(1) In vitro diagnostic manufacturers;

(2) Clinical laboratories regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as qualified to perform high complexity testing under 42 CFR part 493 or clinical laboratories regulated under VHA Directive 1106 (available from Department of Veterans Affairs, Veterans Health Administration, Washington, DC 20420); and

(3) Organizations that use the reagents to make tests for purposes other than providing diagnostic information to patients and practitioners, e.g., forensic, academic, research, and other nonclinical laboratories.

(c) ASR's must be labeled in accordance with § 809.10(e).

(d) Advertising and promotional materials for ASR's:

(1) Shall include the identity and purity (including source and method of acquisition) of the analyte specific reagent and the identity of the analyte;

(2) Shall include the statement for class I exempt ASR's: ''Analyte Specific Reagent. Analytical and performance characteristics are not established'';